

**REMARKS**

Upon entry of the foregoing amendment, claims 1-4 and 7-19 are pending in the application, with claims 1 and 11 being the independent claims. Claim 1 is sought to be amended. Claims 5 and 6 are sought to be cancelled by the present amendment without prejudice to or disclaimer of the subject matter therein. Claims 3, 4, and 18 are currently withdrawn from consideration.

Claim 1 has been amended to delete “sucrose fatty ester” from the claim.

These changes are believed to introduce no new matter, and their entry is respectfully requested. Reconsideration of this application is also respectfully requested.

**I. Rejection of the Claims Under 35 U.S.C. § 102**

The Examiner rejects claims 1 and 2 under 35 U.S.C. § 102(b) as allegedly being anticipated by JP 0558861. (Office Action, at page 2, line 12.) Applicants respectfully traverse this rejection.

Applicants’ invention, as currently claimed, is directed to an oral composition comprising microcrystalline cellulose having an average particle diameter of equal to or smaller than 10 micrometers, and one or more surface active agents selected from the group consisting of alkyl glucoside and betaine. The claimed oral composition exhibits a better shape-holding ability and has better dispersibility in an oral cavity with the specific combination of microcrystalline cellulose and specific surface active agents.

JP 0558861 appears to disclose a toothpaste composition comprising 0.2-10% of microcrystalline cellulose with a particle size in the range of 0.3-6 micrometers. The reference states that the disclosed toothpaste composition exhibits shape retainability and excellent rinsability. JP 0558861, however, fails to disclose the specific surface active agents alkyl glucoside or betaine in combination with microcrystalline cellulose having an average particle diameter equal to or smaller than 10 micrometers, in the disclosed oral compositions.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants respectfully submit that JP 0558861 does not disclose, either expressly or inherently, the specific surface active agents alkyl glucoside or betaine in combination with microcrystalline cellulose. Thus, because P 0558861 does not disclose all the limitations of claims 1 and 2, it cannot anticipate these claims.

The inventors, moreover, have found that the presently claimed oral composition exhibits a better shape-holding ability and dispersibility in an oral cavity when microcrystalline cellulose having an average particle diameter equal to or smaller than 10 micrometers is combined with the specific surface active agents currently recited in claim 1. This effect is demonstrated by the attached declaration of one of the inventors, Akira Nakao (“Nakao Declaration”). The Nakao Declaration demonstrates that a surprising advantage results from specifically combining microcrystalline cellulose having an average particle diameter of equal to or smaller than 10 micrometers with alkyl glucoside or betaine. See Paragraph 5 of the Nakao Declaration.

Applicant believes that the rejection of claims 1 and 2 under 35 U.S.C. § 102(b) has been overcome. Accordingly, Applicant respectfully requests that the Examiner withdraw this rejection.

## **II. Rejection of the Claims Under 35 U.S.C. § 103**

The Examiner rejects claims 1, 2, 7-17 and 19 under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 95/34275 in view of JP 0558861. (Office Action, at page 5, lines 9-10.) Applicant respectfully traverses this rejection.

Specifically, the Examiner indicates that WO 95/34275 does not expressly teach a particle size of 10 microns or lower, and that JP 055861 does not expressly teach the composition further comprising a betaine or a cationic microbial agent. (Office Action, at page 5, lines 12-15.) The Examiner argues that the skilled artisan would have found it obvious at the time of the invention to make the composition suggested in WO 95/34275,

being motivated by the desire to make a smooth creamy composition with good dispersion and shape retention (the latter properties allegedly exhibited by the oral composition disclosed in JP 0558861). (Office Action, at page 5, lines 16-18.)

Applicants respectfully submit that in view of WO 95/34275 and JP 0558861, one of skill in the art would have had no reason to arrive at Applicants' oral composition as currently claimed, *i.e.*, an oral composition comprising the combination of microcrystalline cellulose having an average particle diameter of equal to or smaller than 10 micrometers with a surface active agent selected from the group consisting of alkyl glucoside and betaine.

WO 95/34275 discloses an oral care composition comprising a particulate cellulose cleaning/polishing agent. The composition may contain a surfactant, but it is optional. (See WO 95/34275, at page 7, lines 22-26.) However, as stated in WO 95/34275, at page 4, lines 12-15, although the particulate cellulose "may comprise the powdered and/or microcrystalline type," more suitably, the particulate cellulose "is highly purified powdered cellulose such as that available under the trade names 'Elcema' from Degussa AG and 'Vitacel' from Allchem International." Example 6 discloses a toothpaste composition comprising the cellulose abrasive Elcema (powdered cellulose) and cocamidopropyl betaine.

Applicants draw the Examiner's attention to Fechner *et al.*, *AAPS PharmSci*:5 (4) Article 31, pp. 1-13 (2003), at page 2 (right column); Kleinebudde *et al.*, *AAPS PharmSci*:2 (2) Article 21, pp. 1-10 (2000), at page 2 (right column) and Table 1, and at page 1, Introduction; and "2003 USP NP," pages 2713-2715, which are being submitted concurrently with this Amendment and Reply, in a Supplemental Information Disclosure Statement. These articles indicate that microcrystalline cellulose and powdered cellulose are compounds having entirely different physical properties. WO 95/34275 also distinguishes microcrystalline cellulose from powdered cellulose. See WO 95/34275, at page 2, lines 13-25.

In addition, although WO 95/34275 discloses cellulose having a particle size of from about 1  $\mu\text{m}$  to 350  $\mu\text{m}$  (WO 95/34275, at page 4, second paragraph), the most suitable range is disclosed to be "from about 10  $\mu\text{m}$  to about 100  $\mu\text{m}$ , more suitably from about 20  $\mu\text{m}$  to about 70  $\mu\text{m}$ ." See WO 95/34275, at page 4, line 8.

In contrast, the cellulose contained in Applicants' claimed oral compositions is

microcrystalline cellulose having a relatively low range of average particle diameter, 10 micrometers or less. As described in the current specification: “When the average particle diameter of microcrystalline cellulose is larger than 10 micrometer, dispersibility of the oral composition in the oral cavity is deteriorated” (English-language specification, at page 6, lines 17-19).

Applicants thus submit that WO 95/34275 appears to teach away from using microcrystalline cellulose having a low range of average particle diameter, 10 micrometers or less, in oral compositions. This reference thus appears to teach away from Applicants’ claimed oral compositions.

Regardless of the teachings of WO 95/34275 and JP 0558861, however, Applicants submit that the claimed oral compositions exhibit unexpected effects from incorporation of microcrystalline cellulose with a specific average particle diameter and a specific surface active agent into the composition. See the attached Nakao Declaration, which indicates that a significant effect is exhibited by combining microcrystalline cellulose having an average particle diameter of equal to or smaller than 10 micrometers with the surface active agents alkyl glucoside or betaine. See Paragraph 5 of the Nakao Declaration. As demonstrated in Nakao's declaration, the excellent effect of the present oral composition can be exhibited only by a combination of microcrystalline cellulose having a specific average particle diameter of equal to or smaller than 10 micrometers with these specific surface active agents.

Thus, Applicants respectfully submit that in view of WO 95/34275 and JP 0558861, one of skill in the art would have had no reason to arrive at Applicants’ oral composition as currently claimed. Accordingly, the claimed compositions would not have been obvious in light of WO 95/34275 and JP 0558861.

Applicant believes that the rejection of claims 1-8 under 35 U.S.C. § 103 has been overcome. Accordingly, Applicant respectfully requests that the Examiner withdraw this rejection.

### **CONCLUSION**

Based on the foregoing remarks, Applicants respectfully request that the Examiner reconsider all rejections and that they be withdrawn. Applicants believe that the present

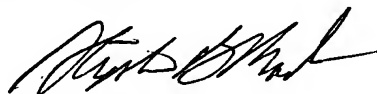
application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 9, 2008

By 

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5569  
Facsimile: (202) 672-5399

Stephen B. Maebius  
Attorney for Applicant  
Registration No. 35,264